Maryland Cardiac Surgery Quality Initiative

June 30, 2014

Via email: paul.parker@maryland.gov
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Maryland Health Care Commission
4160 Patterson Avenue
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RE: Comments regarding the State Health Plan for Facilities and Services: Specialized Health Care Services—Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17)

Dear Mr. Parker:

Thank you and your staff for working with members of the Maryland Cardiac Surgery Quality Initiative (MCSQI) to better understand the proposed regulations for cardiovascular services. We appreciate the opportunity to provide comments on the drafted legislation and hope you consider these remarks as a reflection of the opinions of cardiac surgeons, database managers, hospital administrators, and other healthcare professionals from nine hospitals across the state.

MCSQI's main concern with the proposed regulations regards the transfer of patient-level information from the Society of Thoracic Surgeons' Adult Cardiac Surgery Database (STS-ACSD) to the Maryland Health Care Commission. The drafted regulations state that the submission of this data will help ensure "complete, accurate and fair evaluation of Maryland's cardiac surgery programs." However, it is MCSQI's strongly held opinion that this goal can be accomplished much more efficiently by instead utilizing information from the STS' Quarterly Reports.

As discussed with Eileen Fleck of the MHCC at a meeting on June 23, 2014, the STS-ACSD is renowned as the preeminent clinical database and risk model nationally and internationally. Data validity is ensured by a comprehensive Quality Reporting process, that includes a data collection and entry staff, extensive clinical and scientific database expertise, multiple steps of data validation, and random auditing processes. Database functionality and risk model accuracy fundamentally depend on the size of the data source; the Duke Clinical Research Center (DCRI) is able to provide these services through their statistical expertise and the analysis of more than 4.5 million surgical records.

The methodologies surrounding risk modeling and analysis of such a large data set are of critical importance and can make the difference between accurate, actionable information and incorrect or improper data usage. Expert staff members at DCRI perform calculations on patient-level data to produce a comprehensive summary of risk factors, process measures, and post-operative outcomes across all procedure types. The STS utilizes risk prediction methodologies derived from continually evolving and validated logistic regression models to risk-adjust nine outcomes metrics, providing an objective, continuous quality improvement tool that is among the best of its kind in the world[1] [2] [3]. Both CMS and the National Quality Forum have recognized the STS-ACSD reports as national standards for evaluating the quality of cardiac surgical care.

The STS-ACSD report measures also involve calculations that incorporate data from more than 1,000 surgery practices nationwide. For instance, the STS Star Ratings compare hospitals' risk-adjusted 95% confidence intervals against national

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[1] Shroyer, A.L.W., Grover, F.L., and Edwards, F.H. **1995 Coronary Artery Bypass Risk Model: The Society of Thoracic Surgeons Adult Cardiac National Database.** *Ann Thorac Surg*. 1998; 65: 879–884

[2] Shroyer, A.L.W., Plomondon, M.E., Grover, F.L., and Edwards, F.H. **The 1996 Coronary Artery Bypass Risk Model: The Society of Thoracic Surgeons Adult Cardiac National Database.** *Ann Thorac Surg*. 1999; 67: 1205–1208

[3] Shroyer, A.L.W., Coombs, L.P., Peterson, E.D. et al. **The Society of Thoracic Surgeons: 30-Day Operative Mortality and Morbidity Risk Models.** *Ann Thorac Surg*. 2003; 75: 1856–1864

benchmarks; without the national data set or these proprietary benchmark values, it is impossible to recreate the exact metrics on the STS-ACSD reports[4] [5]. Eileen Fleck has stated that the MHCC could:

1. Purchase the software from an STS-approved vendor, and
2. Use the raw data from programs picked at any time to decide upon the need for a focused program review.

However, the members of MCSQI oppose this premise based on the intricacy of the database and its reports, and the monumental, continual efforts required to create and maintain a national registry used to monitor and improve patient care. Because of the complexity of these calculations, significant differences would exist between the STS-ACSD reports and any calculations MHCC would perform on the patient-level data. These differences in methodology and reporting could lead to inappropriate data usage, resulting in wasted time and resources for providers and ultimately harming the patient population and Maryland residents as a whole.

During the MHCC's Clinical Advisory Group meetings, the group recommended acquiring raw, patient-level data solely for interventional cardiology. The American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) does not provide the same risk-modeled, audited, validated and composite data as does the STS-ACSD. Thus review of these cases is more appropriate, as nationally recognized standards for these cardiology procedures do not yet exist.

If the MHCC were to undertake an analysis of the patient-level STS-ACSD cases, MCSQI would question the potential validity and timeliness of such reports. What additional information would an MHCC-derived report be able to provide above and beyond the comprehensive measures that STS already provides, and at what cost to

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[4] Shahian, D.M., Edwards, F.H., Ferraris, V.A. et al. **Quality Measurement in Adult Cardiac Surgery: Part 1—Conceptual Framework and Measure Selection.** *Ann Thorac Surg*. 2007; 83: S3–S12

[5] O'Brien, S.M., Shahian, D.M., DeLong, E.R. et al. **Quality Measurement in Adult Cardiac Surgery: Part 2—Statistical Considerations in Composite Measure Scoring and Provider Rating.** *Ann Thorac Surg*. 2007; 83: S13–S26

taxpayers? In an era calling for increased fiscal responsibility, we again urge MHCC to consider the time and money involved in analyzing these patient-level data and whether this constitutes a wise utilization of taxpayer resources.

For these reasons, MCSQI recommends the MHCC use the currently available STS reports in lieu of reviewing the patient-level data. A suggested compromise could involve using these reports for an interim period (1-3 years) and then revisiting the prospect of patient-data calculations after MHCC is more familiar with the STS-ACSD, its quarterly reports, and the intricacy within.

Thank you for your consideration,

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